

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

T

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/269,903 05/06/99 WATTS

P WC131

HM12/0121

EXAMINER

PATREA L PABST
ARNALL GOLDEN & GREGORY
2800 ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET
ATLANTA GA 30309-3450

WILLIAMS, P

ART UNIT	PAPER NUMBER
----------	--------------

1616

S

DATE MAILED:

01/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/269,903	Applicant(s) WATTS, PETER JAMES
	Examiner Pernell V. Williams	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) Responsive to communication(s) filed on 06 May 1999.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) 18 and 20 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-22 is/are rejected.
 7) Claim(s) 16 is/are objected to.
 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 a) All b) Some * c) None of the CERTIFIED copies of the priority documents have been:
 1. received.
 2. received in Application No. (Series Code / Serial Number) _____.
 3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|--|--|
| 14) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 19) <input type="checkbox"/> Other: _____ |

Art Unit: 1616

DETAILED ACTION

According to applicant's Preliminary Amendment, filed by this Office on 26 June 1999, claims 18 and 20 have been canceled, and are not available for examination. **Claims 1-17, 19, 21, and 22 are available for examination as amended on the Amendment cited *supra*.**

Information Disclosure Statement

1. The information disclosure statement filed 22 November 1999 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

2. Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 15 claims the steps of: a) making a salt of the drug, and b) coating the salt onto the inner cores. There is no further limitation of the child claim 16, which states that the salt is prepared for the coating of the inner cores. There are no methods conceivable which could

Art Unit: 1616

infringe upon claim 15 and not claim 16. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-14, and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,376,384 (Eichel *et al.*), and further in view of U.S. Patent No. 5,180,832 (Freyne *et al.*).

Art Unit: 1616

Determining the scope and contents of the prior art

Eichel *et al.* discloses as essential components for a controlled release composition comprising all of the following: a core containing a water-soluble drug; a coating by a water-soluble but water impermeable rate-controlling membrane (see column 5, lines 37-45, and claim 1). Said membrane is also EUDRAGIT™ NE30D or ethylcellulose (see column 5, lines 37-45, and claim 3).

Ascertaining the differences between the prior art and the claims at issue

The only difference of note between Eichel *et al.* and the instant application is that the instant application requires that the drug present be the alkali metal salt of ridogrel.

Resolving the level of ordinary skill in the pertinent art

Freyne *et al.* discloses using the alkali metal salt of ridogrel and all (3-pyridinyl)methanone oxime derivatives into a solid controlled release uniform dosage unit (see column 7, lines 4-18 and 37-62, as well as example 32 in text bridging columns 20 and 21). In light of Freyne *et al.*, it would have been obvious to the practitioner of ordinary skill in this art at the time the invention was made to enclose the alkali metal salt of the ridogrel free acid by a water-soluble but water impermeable rate-controlling membrane with reasonable expectation of achieving heightened solubility and controlled release in the ileocolic intestine.

Art Unit: 1616

Considering objective evidence present in the application indicating obviousness or nonobviousness

It is noted that there has not been presented any evidence of record to obviate the rejection cited supra. The disclosures of the components as set forth in the prior art patents are seen to render the instantly claimed composition *prima facie* obvious.

Hence, there is no evidence in the present application to support nonobviousness.

4. Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,376,384 (Eichel *et al.*), and further in view of U.S. Patent No. 5,180,832 (Freyne *et al.*).

Determining the scope and contents of the prior art

Eichel *et al.* discloses coating a drug onto an inner core which is then coated with a rate-controlling membrane which is designed to prevent drug release until the composition reaches the ileocolic region (see column 5, lines 46-67).

Ascertaining the differences between the prior art and the claims at issue

The instant application claims as essential that the drug be present specifically as a salt: preferably the alkali metal salt.

Art Unit: 1616

Resolving the level of ordinary skill in the pertinent art

Freyne *et al.* discloses the conversion of ridogrel and all (3-pyridinyl)methanone oxime derivatives into the alkali metal salt for use in pharmacologic applications (see column 3, lines 11-20). In light of Freyne *et al.*, it would have been obvious to the practitioner of ordinary skill in this art at the time the invention was made to combine the two methods and create a product which will: a) exhibit controlled release in the ileocolic region, and b) treat inflammatory bowel diseases. Thus, in the absence of evidence to the contrary, the expected result is obvious.

Considering objective evidence present in the application indicating obviousness or nonobviousness

It is noted that there has not been presented any evidence of record to obviate the rejection cited supra. The disclosures of the components as set forth in the prior art patents are seen to render the instantly claimed composition *prima facie* obvious. Hence, there is no evidence in the present application to support nonobviousness.

Conclusion

Claims 1-22 are not allowed.

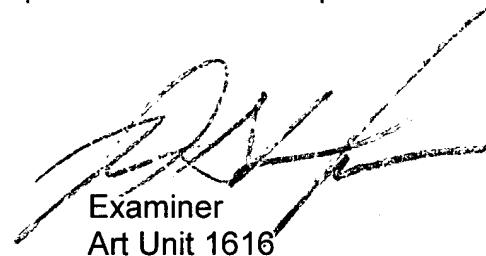
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pernell V. Williams, whose telephone number is

Art Unit: 1616

(703) 308-4645. The examiner can normally be reached from 9AM to 4:30PM Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Examiner
Art Unit 1616

pvw
January 11, 2000

JOSÉ G. DEES
SUPERVISORY PATENT EXAMINER